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EXAMINER

TOUZEAU, L.

18M2/1004

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ART UNIT PAPER NUMBER

1618

DATE MAILED:

10/04/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined Responsive to communication filed on 8-24-95 This action is made final.A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice re Patent Drawing, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, Form PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6. ER Evt. Summary

Part II SUMMARY OF ACTION

1. Claims 1-14 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 8 ⁶⁶ have been cancelled.3. Claims 1-7 and 9-11 add. 13-14 are allowed.4. Claims 12 ⁶⁵ rejected.5. Claims _____ are objected to.6. Claims _____ are subject to restriction or election requirement.7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.8. Formal drawings are required in response to this Office action.9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948).10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).11. The proposed drawing correction, filed on _____, has been approved. disapproved (see explanation).12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.14. Other

EXAMINER'S ACTION

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15. Applicant's arguments have been fully considered, but have not been found to be convincing with respect to claim 12.

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claim 12 is rejected under 35 U.S.C. § 103 as being unpatentable over Meyers et al. (Meyers). Meyers discloses a large scale adaptation of a recently reported glycine precipitation method for the production of Factor VIII:C concentrate. This method includes adding aluminum hydroxide to a glycine buffer to reduce the level of protein contamination in the final preparation. Furthermore, the resultant product was virus-inactivated by the incorporation of the organic solvent and detergent (TNBP and T80) (abstract). At the industrial level, this method gave 185 IU of FVIII:C activity per liter of starting plasma, which the Examiner deems to be at least equivalent to Applicants' yield. Although he does not teach a pharmaceutical containing a solution, he does teach that his concentrate is considered to be suitable for clinical use (page 146, column 1, last 3 lines). Thus, the preparation of a solution with Factor VIII:C activity containing a basic amino acid such as glycine and a nonionic detergent containing a high activity for clinical use would have been

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obvious. One of ordinary skill in the art would have been motivated to prepare a solution of Factor VIII:C using Meyers' glycine precipitation method and, therefore, the process claim, claim 12 is not allowable.

It would have been obvious to employ either a detergent or an organic polymer as both are known in the art.

18. Claim 13 is allowable because it was rewritten or amended to overcome the rejection under 35 U.S.C. §112, second paragraph.

19. The rejection made under 35 USC 103 of claims 1-7, 9-11, 13 and 14 in paper No. 15 has been withdrawn in light of applicants' arguments and discussion in the amendment received in this Office 24 August 1995.

Any inquiry concerning this communication should be directed to P. Lynn Touzeau, Ph.D at telephone number (703) 308-0196.

PLT 29 September 1995

[Signature]

HOWARD E. SCHAIN
SENIOR LEVEL EXAMINER
GROUP 1800

Howard E. Schain